


K963705

DEC - 3 1996

510(k) Summary

Submitter's Name: Toshiba America Medical Systems, Inc.
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Establishment Registration Number: 2020563

Device Proprietary Name: Color Enhancement Function for the SSA-380A
Common Name: Amplitude Doppler
Classification Name: Ultrasonic Pulsed Doppler Imaging System Accessory
[Fed. Reg. No.: 892.1550, Pro. Code: 90-IYN]
Device Track: Track 3

Regulatory Class: II 
514 Performance Standards: None
Special Controls: None
Prescription Status: Prescription Device

Reason for Submission:
Modification of the SSA-380A

Substantial Equivalence Summary:

Color Angio is a post-processing modification to the Power Mode display that was cleared with the SSA-380A system in K933743. It is an amplitude based color display subset of color doppler imaging that performs frame addition to accentuate minute vascular structures and signal the presence of blood, rather than the motion of flow. This feature is independent of velocity, angle of incidence and direction of interrogation and reduces the effects of aliasing. It